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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,718	01/03/2002	David S. Hungerford	21418-PA-DIV	4599

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06/24/2004

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/039,718	Applicant(s) HUNGERFORD ET AL.	
	Examiner David M. Naff	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

A preliminary amendment of 1/3/02 amended the specification, and added new claims 36-83.

Claims in the application are 1-83.

5 Restriction to one of the following inventions is required under
35 U.S.C. 121:

- I. Claims 1-6, drawn to a method of cell culture on dextran microcarrier beadlets, and separating the cells from the beadlets by digestion with dextranase, and to a method
10 wherein the cells are chondrocytes, after separating from the beadlets, the chondrocytes are plated on a scaffold and the scaffold is implanted, and to a method of separating cells from the microcarrier beadlets and injecting the cells into a patient, classified in class 424, subclass 93.7.
- 15 II. Claims 7-20, drawn to a crosslinked polysaccharides for cell culture or use as a template for tissue replacement prepared by crosslinking a polysaccharide with a polyamine, and to methods of using the crosslinked polysaccharide to culture cells for surgical repair of cartilage, classified in class
20 424, subclass 488.
- III. Claims 21-27, 29 and 30, drawn to scaffolds comprising chitosan and to methods of implanting the scaffold for tissue repair, classified in class 424, subclass 493.
- IV. Claim 28, drawn to a method of surgically implanting
25 chondrocytes, classified in class 424, subclass 423.

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V. Claims 31 and 32, drawn to a method of obtaining increased levels of collagen type II chondrocytes by culturing chondrocytes at low oxygen tension, classified in class 435, subclass 325.

5 VI. Claim 33, drawn to a surgical procedure wherein chondrocytes are taken from a patient, rapidly multiplied and transplanted into a patient, classified in class 424, subclass 426.

10 VII. Claim 34, drawn to a method for making a scaffold for tissue repair by culturing chondrocytes on a chitosan scaffold in the presence of integrins, classified in class 435, subclass 178.

15 VIII. Claim 35, drawn to a method of preparing a scaffold for tissue repair by culturing chondrocytes on a chitosan scaffold at low oxygen tension, classified in class 435, subclass 395.

20 IX. Claims 36-46 and 58-70, drawn to a method of repairing tissue by obtaining a chondrocyte specimen or tissue specimen from a different part of a patient's body, rapidly growing the chondrocytes or cells from the tissue externally of the body in spin-culture on microcarrier beads, and implanting the rapidly grown chondrocytes or cells, classified in class 424, subclass 422.

25 X. Claims 47-57 and 71-83, drawn to a method of repairing tissue by obtaining a chondrocyte specimen or tissue

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specimen from a different part of a patient's body, rapidly growing the chondrocytes or cells from the tissue externally of the body in a low oxygen-environment, and implanting the rapidly grown chondrocytes or cells, classified in class
5 424, subclass 548.

The inventions are distinct, each from the other because:

The methods of inventions I-X each require different steps and/or components such that each can be performed to produce a different result without any of the other methods.

10 The crosslinked polysaccharide of invention II and chitosan scaffold of invention III can have a use other than implanting to produce tissue such as to culture cells *in vitro* to produce a metabolic product of the cells. The crosslinked polysaccharide does not contain chitosan, and the chitosan scaffold does not contain the
15 crosslinked polysaccharide.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

20 Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance
25 with 37 CFR 1.48(b) if one or more of the currently named inventors is

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no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5 The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or**
10 **otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116;
15 amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable,
20 the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in
25 scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the
30 process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply
35 where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier
40 communications from the examiner should be directed to David M. Naff

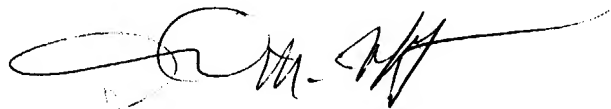
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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-

5 0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained
10 from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-
15 9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
6/22/04